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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,583	01/12/2004	Jeffrey Kozak	4002-3420	9189
30565	7590	10/04/2005	EXAMINER	
WOODARD, EMHARDT, MORIARTY, MCNETT & HENRY LLP BANK ONE CENTER/TOWER 111 MONUMENT CIRCLE, SUITE 3700 INDIANAPOLIS, IN 46204-5137			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	10/755,583	KOZAK ET AL.
	Examiner	Art Unit
	Anu Ramana	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 13-21 and 25-44 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 25-31 is/are allowed.
- 6) Claim(s) 13, 14, 16, 19-21, 32, 33 and 41-44 is/are rejected.
- 7) Claim(s) 15, 17, 18 and 34-40 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-33 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The limitation, "steps of providing a set of screws" is held to be new matter since the disclosure as originally filed does not disclose this step.

Claim Rejections - 35 USC § 102

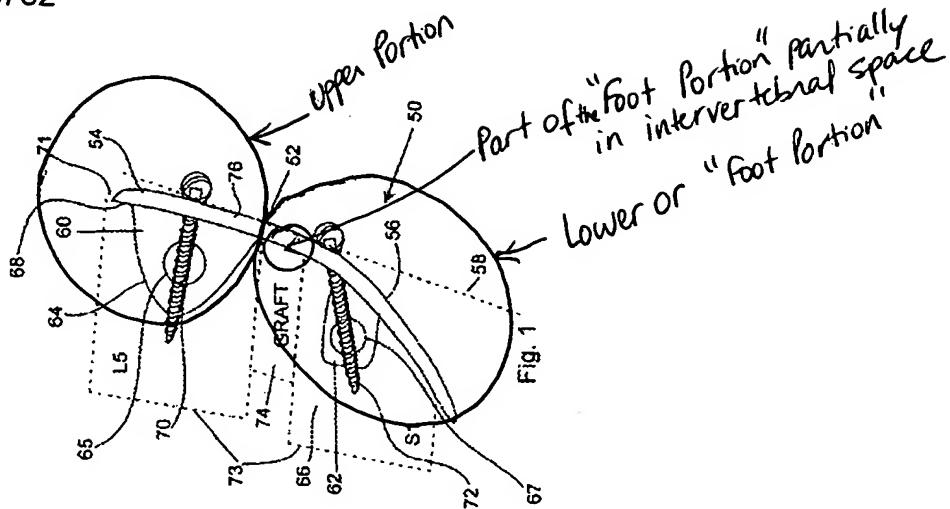
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Zucherman et al. (US 6,045,552).

Zucherman et al. disclose a plate for use in immobilizing L5, S1 vertebrae having: a foot portion partially in the intervertebral space; screws 65 in the upper portion of the plate, fixing the plate to an L5 vertebra; and screws 72 extending downwardly from the front through the bottom of the foot portion into S1 (Fig. 1, col. 3, lines 22-67 and col. 4, lines 1-16). See marked up Figure 1 on following page.



The claimed method steps are inherently performed during normal use of the Zucherman et al. fixation plate for the purpose of immobilizing L5, S1 vertebrae.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US 6,045,552) in view of Freid et al. (US 6,331,179).

Zucherman et al. disclose all elements of the claimed invention except for screws 72 installed on convergent paths and anti-backout devices.

Regarding claim 16, Zucherman et al. disclose bone graft 74 inserted in the intervertebral space between L5 and S1 vertebrae (col. 4, lines 9-16).

Freid et al. teach installing screws on converging paths to prevent screw backout (Fig. 3 and col. 1, lines 41-52). Freid et al. also teach the use of mechanisms for anchoring or locking fastener heads to prevent backout of fasteners (col. 2, lines 32-37 and lines 55-67 and col. 3, lines 1-16).

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Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have installed screws 72 in the Zucherman et al. plate on convergent paths, as taught by Freid et al., to prevent screw backout.

Claims 14, 20-21 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (US 6,045,552) in view of Michelson (US 6,193,721).

Zucherman et al. disclose all elements of the claimed invention except for screws 72 installed on convergent paths and anti-backout screws.

Michelson teaches screws installed on convergent paths and an anti-backout screw 21 with a conical head adapted to engage and interlock the surfaces of screws 30 to prevent backout of screws 30 from a plate (Fig. 43, col. 8, lines 12-24 and col. 26, lines 17-20).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have installed screws 72 in the Zucherman et al. plate on convergent paths and to have provided an anti-backout screw, as taught by Michelson, to prevent screw backout.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on July 20, 2005 are not persuasive with respect to claims

Regarding claim 13, Zucherman et al. clearly show a foot portion, or "lower part" of the plate assembly partially in the intervertebral space as previously discussed.

Regarding claims 14, 16 and 19, Applicants' arguments are not persuasive since the limitation "on convergent paths" only requires that the shaft axes of the screws be inclined with respect to each other and does not require that the screw shafts crossover. Thus, keel 62 would not interfere with screws 72 and 80 in the device of the combination of Zucherman et al. and Freid et al. Note also that Figure 2 of Zucherman et al. shows keel 62 positioned below the screw holes.

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In response to applicant's argument that there is no suggestion to combine Zucherman et al. and Freid et al., the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Freid et al. clearly teach angling fasteners in converging directions to prevent backout (col. 1, lines 40-50).

Allowable Subject Matter

Claims 15, 17-18 and 34-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 25-31 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-

4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Annabella Ramane*
September 28, 2005



EDUARDO C. ROBERT
PRIMARY EXAMINER